IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

CEPHALON, INC. and CIMA LABS, INC.,	)	
Plaintiffs,	)	
v.	)	Civ. No. 10-123-SLR
SANDOZ INC.,	)	
Defendant.	)	

MEMORANDUM ORDER

At Wilmington this 5th day of May, 2011, having considered plaintiffs' motion to stay proceedings and the papers submitted in connection therewith;

IT IS ORDERED that said motion (D.I. 88) is granted, for the reasons that follow:

1. **Background**. This is a Hatch-Waxman suit in which Cephalon, Inc. and CIMA Labs, Inc. (collectively, "Cephalon") assert infringement of U.S. Patent Nos. 6,200,604 ("the '604 patent") and 6,974,590 ("the '590 patent") (hereinafter, collectively "the Khankari patents") against Sandoz, Inc. ("Sandoz"). Cephalon is the holder of an approved New Drug Application ("NDA")[1] for the manufacture and sale of fentanyl buccal tablets for the treatment of breakthrough cancer pain. Cephalon sells its fentanyl buccal tablets under the brand name Fentora®. Cephalon listed with the Food and Drug Administration ("FDA") the '604 and '590 patents in the Orange Book in connection with its NDA. Sandoz has submitted an Abbreviated New Drug Application

[1]No. 21-947.

("ANDA")[2] to the FDA for generic fentanyl buccal tablets. In response to Sandoz's ANDA filing, which contained a paragraph IV certification as to the '604 and '590 patents,[3] Cephalon filed a patent infringement suit on February 16, 2010.[4] (D.I. 1)

2. Cephalon previously brought suit against Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., and Watson Pharma, Inc. (collectively, "Watson") in this court for infringement of the Khankari patents by submission of Watson's ANDA[5] for generic fentanyl buccal tablets. (Civ. No. 08-330) Following a bench trial on infringement and validity, the court issued its findings of fact and conclusions of law in that case on March 11, 2011. (*Id.*, D.I. 327) In its opinion, the court found that Cephalon did not demonstrate infringement by Watson and found both Khankari patents invalid for lack of enablement. (*Id.*)

3. In a separate litigation, Cephalon, Inc. asserted U.S. Patent No. 6,264,981 ("the '981 patent") against Watson. (Civ. No. 09-724) The '981 patent was not listed in the Orange Book for Fentora®. Following a bench trial, on March 24, 2011, the court found that Cephalon met its burden of proof on infringement by Watson's generic product and that Watson had failed to prove invalidity by clear and convincing evidence. (*Id.*, D.I. 194) On the parties' stipulation, the court entered a permanent injunction

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[2]No. 200676.

[3]*See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

[4]*See* 35 U.S.C. § 271(e)(2)(A) ("(2) It shall be an act of infringement to submit – (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent[.]").

[5]No. 79-075.

barring Watson (or its agents, successors and assigns) from infringing the '981 patent through its release of a generic fentanyl buccal product until the expiration of the '981 patent.[6] (*Id.*, D.I. 204) The '981 patent was filed in October 1999, and should expire in October 2019.

4. The parties agree that Sandoz is the second generic filer behind Watson for generic fentanyl buccal tablets.[7] Discovery in the case at bar has proceeded and is now closed. (D.I. 93 at 49[8]) Cephalon represents that the 30-month stay expires in July 2012. (D.I. 89 at 2) The FDA has not yet approved Sandoz's ANDA. The parties have submitted a joint claim construction statement and opening claim construction briefs in this case. Trial is currently scheduled to commence June 6, 2011. Cephalon filed its motion to stay the present litigation on March 29, 2011. (D.I. 88)

5. **Standard**. Motions to stay invoke the broad discretionary powers of the court. *See Dentsply Int'l, Inc. v. Kerr Mfg. Co.*, 734 F. Supp. 656, 658 (D. Del. 1990) (citing *Bechtel Corp. v. Laborers' Int'l Union*, 544 F.2d 1207, 1215 (3d Cir. 1976)). Three general factors inform the court in this regard:

> (1) whether the granting of a stay would cause the non-moving party to suffer undue prejudice from any delay or allow the moving party to gain a clear tactical

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[6]The FDA approved Watson's ANDA on January 7, 2011; the court entered an injunction preventing Watson from releasing its generic pending resolution of the litigation.

[7]There are filers behind Sandoz as well. On February 24, 2011, Cephalon sued Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, "Mylan") for infringement of the Khankari patents arising out of Mylan's filing of an ANDA (No. 202577) for generic fentanyl buccal tablets. (Civ. No. 11-164, D.I. 1) No schedule has been set in the Mylan action.

[8]All docket items hereinafter reference Civ. No. 10-123 unless otherwise noted.

advantage over the non-moving party; (2) whether a stay will simplify the issues for trial; and (3) whether discovery is complete and a trial date set.

Enhanced Security Research, LLC v. Cisco Sys., Inc., Civ. A. No. 09–571, 2010 WL 2573925, at *3 (D. Del. June 25, 2010) (citing *St. Clair Intellectual Prop. Consultants v. Sony Corp.*, Civ. A. No. 01–557, 2003 WL 25283239, at *1 (D. Del. Jan. 30, 2003)).

6. **Discussion**. While discovery is complete and trial imminent, the first two factors favor the imposition of a stay in this case. A stay will simplify the issues for trial. The court has already found the Khankari patents invalid. The parties appear to agree that the Federal Circuit will have completed its review and disposition of Cephalon's appeal in the Watson litigation before July 2012, when the 30-month expires in this case. If the Federal Circuit affirms the court's invalidity holding, there is no reason for trial and the expenses related thereto.

7. Further, a stay would not unduly prejudice Sandoz under the circumstances. The FDA has not yet approved its ANDA and, until the 30-month stay expires in July 2012, Sandoz cannot enter the marketplace.[9]

8. Sandoz suggests that a stay will affect its ability to petition the FDA to terminate Watson's exclusivity rights, as follows. Watson may be awarded up to 180 days exclusivity as the first generic filer, at the FDA's discretion. The parties recognize that the FDA may deem Watson to have forfeited its exclusivity rights for a number of

[9]*See* 21 U.S.C. § 355(j)(5)(B)(iii). The court makes every effort to render its decisions prior to the expiration of the stay, but may not, due to its taxed judicial resources, render a decision with significant time to spare.

reasons.[10] Notably, if Sandoz receives a favorable court judgment **and** final ANDA approval, it could enter the market before Watson, which remains enjoined from manufacturing its generic fentanyl buccal tablets until the expiration of the '981 patent. In that situation, the FDA may declare a forfeiture and allow Sandoz to enter the market. (D.I. 98 at 16-17)

9. The foregoing scenario is possible only if the Federal Circuit affirms each of the court's rulings (that the Khankari patents are invalid as a matter of law and the '981 patent is valid and infringed by Watson).[11] A stay of these proceedings does not affect the Watson appeal, which remains the fastest and most direct path to Sandoz's launch. By contrast, Sandoz's argument that a stay will ultimately compromise its ability to contest Watson's exclusivity award is largely speculative at this juncture.

10. Sandoz also emphasizes the following issues in this action which were not resolved in the Watson case: (1) claim construction of "increase absorption"; (2) Sandoz's indefiniteness argument with respect to "in an amount sufficient [to increase absorption]"; and (3) Sandoz's argument that its ANDA product does not infringe the '604 patent based on its label instructions. Sandoz also asserts that, in the event the court's judgment of invalidity is reversed, it will have lost its 2011 trial date in favor of a 2012 or 2013 date by that time. While this is possible, this case could proceed to disposition on the remaining issues with the benefit of the Federal Circuit's rulings on

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[10]For example, because Watson did not obtain tentative approval within 30 months of filing its ANDA. (D.I. 89 at 7, n.6; D.I. 98 at 16)

[11]An assumption the court declines to make given the Federal Circuit's reversal rate in complex patent cases.

claim construction and other issues. A narrowing of the issues to be tried following Cephalon's appeal may also facilitate the court's rescheduling of the trial.

11. **Conclusion**. For the foregoing reasons, the court agrees with Cephalon that a stay of this litigation is warranted pending appeal of the Watson cases (Civ. Nos. 08-330, 09-724).

United States District Judge